

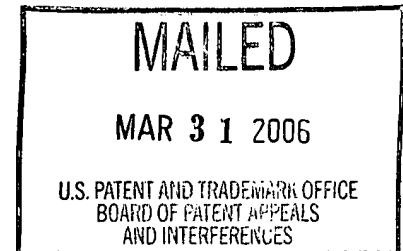
The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte SE-JIN LEE, THANH HUYNH  
and SUZANNE SEBALD

Appeal No. 2005-2385  
Application No. 09/485,045



ON BRIEF

Before SCHEINER, MILLS, and GRIMES Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 2, 4-11 and 53-55. Claim 2 is representative and reads as follows:

2. An isolated polynucleotide sequence encoding the growth differentiation factor -16 (GDF-16) polypeptide as set forth in SEQ ID NO:2.

The reference cited by the examiner is:

J. Massagué (Massagué), "TGF- $\beta$  Signal Transduction," Ann. Rev. Biochem., Vol. 67, pp. 753-791 (1998)

The references cited by the appellants are:

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Tabibzadeh et al ('751) 5,916,751 June 29, 1999  
(Filed Aug. 27 1997)

Tabibzadeh et al. (Tabibzadeh) "Distinct Tumor Specific Expression of TGFB4 (ebaf), A Novel Human Gene of the TGF- $\beta$  Superfamily," Frontiers in Bioscience 2, Vol. 2, pp. a18-25, (1997)

Kothapalli et al., (Kothapalli) "Detection of ebaf, a Novel Human Gene of the Transforming Growth Factor  $\beta$  Superfamily," J. Clin. Invest., Vol. 99, No. 10, pp. 2342-2350 (1997)

### Grounds of Rejection

Claims 2, 4-11 and 53-55 stand rejected under 35 U.S.C. §101 for lack of utility.

Claims 2, 4-11 and 53-55 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement.

We reverse these rejections.

### DISCUSSION

#### Utility and Enablement

Claims 2, 4-11 and 53-55 stand rejected under 35 U.S.C. §101 for lack of utility.

Claims 2, 4-11 and 53-55 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement.

In support of the rejection for lack of utility, the examiner argues (Answer, pages 3-4)

[t]he claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. ... While Appellant lists a number of conditions for which the protein encoded by the GDF-16 polynucleotide might be used (p. 5 and 6), the specification does not disclose any activity known to be associated with it. .... [N]o diseases or

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conditions with which the protein is associated are disclosed; thus, there is no "specific benefit in currently available form" to be derived from detection of GDF-16 or inhibition of its activity.

With respect to enablement, the examiner argues that "one skilled in the art clearly would not know how to use the claimed invention" "since the claimed invention is not supported by either a specific or substantial utility." *Id.*, page 4. As evidence of lack of utility and enablement, the examiner puts forth Massagué. The examiner argues,

Massagué (Ann. Rev. Biochem., 1998, vol. 67, pp. 753-791) teaches that 'this family comprises a large number of... factors, each capable of regulating a fascinating array of cellular processes...' (p. 745). Even those family members identified as GDFs have functions as varied as the promotion of chondrogenesis and the inhibition of muscle growth (p. 755). There is therefore no well-established utility for members of this family; they are involved in many different processes and utility is specific to the individual protein.

Answer, page 4.

On the other hand, appellants argue the utility for the claimed polynucleotide and polypeptide sequence is present in the specification, as filed. Appellants argue (Brief, page 5)

[t]he specification discloses that GDF-16 is a TGF-beta family member. Based on this fact and the known activities of various TGF-beta family members, a number of utilities were asserted for GDF-16 encoding polynucleotides, [and] ... are supported by published literature. ... More specifically, the specification discloses that a GDF-16 polynucleotide can be utilized in detecting and diagnosing a cell proliferative disorder by detecting an altered level of expression compared with that of a normal cell (page 19, lines 3-10). Furthermore, the specification discloses that a GDF-16 polynucleotide can be used to detect a close family member of GDF-16 (page 7, lines 18-23).

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Appellants further argue, (Brief, pages 5-6 )

A number of scientific publications available as of the filing date of the present application, describe specific expression of TGF $\beta$  family members, for example the TGF $\beta$ -4 (endometrial bleeding associated factor; 'ebaf') gene, in cell proliferative disorders, including endometrial bleeding and adenocarcinoma of the colon, ovaries, and testes (see Kothapalli et al. *J. Clin. Invest.* 99,2342-2350 (May 15, 1997); and Tabibzadeh et al., *Frontiers in BioScience* 2, a18-25 (July 15, 1997)[]). ... [T]he polynucleotide sequence of TGF $\beta$ -4 (ebaf), disclosed in US. Pat. No. 5,916,751 (The '751 Patent), contains a region of 303 nucleotides that is 92% homologous to SEQ ID NO: 1 of the subject application. ... Applicants submit that one skilled in the art, viewing the subject application, and having knowledge of the Kothapalli et al. and Tabibzadeh et al. references, would immediately appreciate that the polynucleotides of the invention ... are useful in the detection of TGF $\beta$  family members, such as TGF $\beta$ -4 (ebaf), whose expression is correlated with cell proliferative disorders.

We agree with appellants that one of ordinary skill in the art, viewing the subject application and having knowledge of the '571 patent and Kothapalli and Tabibzadeh references, would appreciate that the claimed GDF-16 polynucleotide would have been useful in the detection of TGF $\beta$  family members, such as TGF $\beta$ -4 (ebaf), whose expression is correlated with cell proliferative disorders.

An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible. See, e.g., In re Folkers, 344 F.2d 970, 145 USPQ 390 (CCPA 1965). “[U]sefulness of a chemical compound is invariably a manifestation of a given property of that compound. ... [S]ome uses can be immediately inferred from a recital of certain properties. The question here is ... whether knowledge

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of that property necessarily and implicitly renders it readily apparent to one of ordinary skill that the present compounds are useful." Id., 344 F.2d at 972, 145 USPQ at 393. The courts have also repeatedly held that all that is required is a reasonable correlation between the activity and the asserted use. Nelson v. Bowler, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).

In the present case, the utility of GDF-16 is a manifestation of its homology with ebaF. In the present case we do not find that the examiner has given appropriate consideration to the understanding gleaned by one of ordinary skill in the art reading the present disclosure in the context of the state of the prior art. In our view, appellants' evidence establishes it was known in the art that the nucleotide sequence of TGF $\beta$ -4 (ebaF) was correlated with cell proliferative disorders. See '517 patent, abstract. In addition, one of ordinary skill in the art reading appellants' specification and becoming aware of the nucleotide and amino acid sequences of GDF-16 would have understood that the 303 nucleotide sequence of GDF-16 and/or complements thereto could be used for detection of the ebaF gene and its associated cell proliferative disorders in view of GDF-16's 92% homology with a relatively large portion of the ebaF gene.

The examiner fails to acknowledge the correlation between the homology of the claimed GDF-16 sequence to the known ebaF gene, associated with cell proliferative disorders. In our view, the state of the prior art and the meaning of the disclosure when viewed through the eyes of one of ordinary skill in the art supports the utility of the claimed invention.

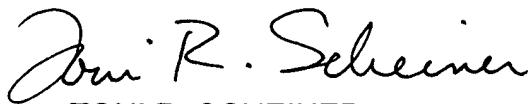
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In view of the above, we reverse the rejection of the claims for lack of utility and closely associated rejection of the claims for lack of enablement.

CONCLUSION

We therefore reverse the rejections of claims 2, 4-11 and 53-55 under 35 U.S.C. §101 for lack of utility and under 35 U.S.C. §112, first paragraph for lack of enablement.

REVERSED



TONI R. SCHEINER  
Administrative Patent Judge

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DEMETRA J. MILLS  
Administrative Patent Judge

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ERIC GRIMES  
Administrative Patent Judge

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